

## Certificate of Analysis

**Product name:** **Acidum citricum monohydricum**

**Batch number / Weight:** **23K06-B02-236484 / 250 G**

**Analysed according to:** **Ph.Eur.11.3**

**Number of analysis / Inspection Code** **23K06-B02 / INS-24-0010**

**Reference Code / No.:** **V01192 / UJ333**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(almost) white, crystalline powder, colourless crystals or granules, efflorescent	Conform		
Identification B	Conform	Conform		
Identification E	7,5 - 9,0	8,50		
Appearance of solution	Clear <=Y7, BY7 or GY7	Conform		
Readily carbonisable substances	Conform	Conform		
Oxalic acid	<=360	<360	ppm	
Sulphates	<=150	<150	ppm	
Aluminium	<=0,2	<0,1	ppm	
Water (Karl Fischer)	7,5 - 9,0	8,50	%	
Sulphated ash	<=0,1	0,00	%	
Assay Citric acid	99,5 - 100,5 (anhydrous substance)	99,82	%m/m	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Endotoxins	< 0,5	<0,5	IU / mg	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Total aerobic microbial count (TA)	<=10 <sup>3</sup>	Conform	CFU/g	
Total yeasts and moulds (TYMC)	<=10 <sup>2</sup>	0	CFU/g	

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All the manufacturing stages of this batch have been carried out in full compliance with the GMP requirements of the EU and with the national legal requirements.

Analysis performed by the authorized lab Fagron PL, EI Spol

Release:

Agnieszka Pszczółka

Qualified Person

25-01-2024

Expiration: 14-08-2026

Conclusion: APPROVED

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